

I. *Oath/Declaration*

The Office objects to the originally-filed Declaration of the inventor for lacking an indication of the citizenship of the inventor. (Office Action at page 2.) Applicant requests that the Office hold this objection in abeyance. A properly executed Declaration is in preparation and will be submitted as soon as it is completed.

II. *Specification*

The Office objects to the specification for including "blanks" on pages 5, 6, 14, 15, and 16. (Office Action at page 2.) Applicant affirms the prior statement, submitted in the Amendment filed 12 November 2009, that the blanks serve a purpose at this point in prosecution, and that they will be completed by Applicant upon an indication that the application is in condition for allowance. Applicant requests that the Office hold this objection in abeyance until that time.

III. *Rejection Under 35 U.S.C. § 112, first paragraph*

The Office rejects claim 35 under 35 U.S.C. § 112, first paragraph, for reciting a specific host cell that must be either publicly available or obtainable by a repeatable method, but for which a Deposit Number and agency is not provided. (Office Action at pages 2-3.) Applicant is in the process of perfecting the deposit and preparing the required statement. Applicant accordingly requests that the Office hold this rejection in abeyance until the appropriate actions are taken.

IV. *Rejections Under 35 U.S.C. § 103*

A. Saiga

The Office rejects claims 1, 2, 4, 5, 7-9, 13-18, 24, and 31 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,090,783 to Saiga et al. ("Saiga"). (Office Action at pages 4-7.) The Office asserts that it would have been obvious to one of ordinary skill in the art to place the splice acceptor and/or splice donor site(s) at any position along the nucleic acid construct as long as the goal of *Saiga* (production of a desired protein as a result of viral infection, and repression of expression in the absence of virus due to excision as a result of intron removal).

Applicant acknowledges the Office's position, but requests that the Office reconsider Applicant's prior argument against obviousness.

Specifically, the Office contends that, absent unexpected results, it would have been obvious to place the donor/acceptor sites anywhere on the construct as long as the primary goal of *Saiga* is achieved. Applicant submits that the presently claimed position for the splice acceptor is, in fact, an unobvious site for the splice acceptor because such positioning provides an unexpected result. As previously argued, because both the splice acceptor and the RRE element have specific sequence requirements for their function, one of ordinary skill in the art would expect that creation of a splice acceptor site within an RRE site would reduce or abolish the function of one or both of the splice acceptor and RRE. As such, one of skill in the art would avoid making a construct as recited in the present claims. In essence, the presently claimed invention proceeds in a manner that is contrary to the manner in which a person of ordinary skill in the art would proceed, and provides a result that is unexpected.

Applicant disagrees with the Office's position that it would have been obvious to place the splice acceptor "in any location". Applicant submits that, while one of ordinary skill in the art might find it obvious to select various different locations for placement of the splice acceptor site, one location that would immediately be identified as a location where the splice acceptor should not be located would be within the RRE.

For at least this reason, Applicant requests that the Office reconsider and withdraw the rejection of claims 1, 2, 4, 5, 7-9, 13-18, 24, and 31 under 35 U.S.C. § 103(a) as unpatentable over *Saiga*.

B. Corbeau In View Of Hope, D'Costa, and Saiga

The Office rejects claims 1-5, 7-18, 24, and 31 as unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,323,019 to Corbeau et al. ("Corbeau") in view of U.S. Patent No. 6,136,597 to Hope et al. ("Hope"), D'Costa et al. ("D'Costa"), and *Saiga*. (Office Action at pages 8-11.) The Office relies on *Saiga* for the teachings described above, and relies on *Corbeau* for a teaching of the use of an SV40 promoter, a splice donor/acceptor combination, an expressible sequence, and an RRE from HIV. The Office relies on *Hope* for a teaching of the use of mammalian promoters in certain expression constructs, and relies on *D'Costa* for a teaching of the use of packaging signals for packaging of viral particles. Importantly, the Office recognizes that none of the cited references teaches placement of a splice acceptor site within an RRE.

The non-obviousness of the location of the splice acceptor site according to the presently claimed invention is discussed above with regard to *Saiga* and has been previously discussed with regard to that reference and the remaining references cited in this rejection. Applicant

submits that none of *Corbeau*, *Hope*, *Saiga*, or *D'Costa*, alone or in combination, discloses or suggests placement of a splice acceptor site within an RRE site. As discussed above, such a placement is contrary to common wisdom and as such provides an unexpected result. For at least this reason, Applicant requests that the Office reconsider and withdraw the rejection of claims 1-5, 7-18, 24, and 31 as unpatentable under 35 U.S.C. § 103(a) over the combination of *Corbeau*, *Hope*, *Saiga*, or *D'Costa*.

C. Saiga In View Of Corbeau And D'Costa

The Office rejects claim 19 as unpatentable under 35 U.S.C. § 103(a) over *Saiga* in view of *Corbeau* and *D'Costa*. (Office Action at page 11.) The Office relies on *Saiga*, *Corbeau*, and *D'Costa* for the teachings discussed above, and further relies on *D'Costa* for a teaching regarding the use of IRES in constructs. Applicant submits that the combination of references has been discussed above, and the deficiencies in the teachings identified. For the reasons set forth above with regard to the other rejections under this statute and paragraph, Applicant submits that claim 19 is patentable. Accordingly, Applicant requests that the Office reconsider and withdraw the rejection of claim 19 as unpatentable under 35 U.S.C. § 103(a) over *Saiga* in view of *Corbeau* and *D'Costa*.

V. Allowable Subject Matter

The Office indicates that claim 22 is allowable. Applicant thanks the Office for this indication, and submits that the remaining claims are in condition for allowance as well.

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VI. *Request for Interview*

Applicant hereby requests that, prior to any further Office Actions, the Office meet with Applicant's undersigned representative to discuss the application and any further perceived issues that would preclude allowance of the application.

VII. *Conclusion*

Applicant submits that this application is in condition for allowance, and such action is requested. As requested above, if the Office believes anything else is necessary to place the application in condition for allowance, Applicant requests that the Office contact Applicant's undersigned representative.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 50-2961.

Respectfully submitted,
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